K033424

DEC 1 1 2003

510(k) Summary of Safety and Effectiveness in Accordance with SMDA'90

October 22, 2003

Transonic Systems Inc.
34 Dutch Mill Road
Ithaca, NY 14850
Telephone Number: (607) *257-5300*
Fax: (607) 257-7256
Contact: Mark S. Alsberge

Establishment Registration Number: 1319030

Product Name: Transonic Anglo Flow Meter and Catheter
Trade Name: Thermodilution meter and catheter
Classification name:

Cardiovascular Blood Flowmeter
Cardiovascular
Class II, 74 DPW
21 CRF *§870.2100*

SUBSTANTIAL EQUIVALENCE TO:

510 (k) Number	Name	Applicant
K010253	Transonic Anglo Flow Meter and Catheter	Transonic Systems Inc.

Device Description:

In accordance with section 510(k) for the Federal Food, Drug, and Cosmetic Act, Transonic Systems Inc. intends to introduce into interstate commerce the Transonic Angio Flow Meter and Catheter which is intended for the measurement of blood flow within a vascular bed utilizing a catheter-based sensor. This sensor system uses thermal changes induced by a bolus injection of normal saline and thermal-dilution principles to calculate blood flow in hemodialysis grafts.

Indications for Use:

The Transonic Angio Flow Meter and Catheter indicated for use during angioplasty procedures to verify the flow before, during and after treatment. The system is intended for the measurement of blood flow within a vascular bed utilizing a catheter-based sensor. This sensor system uses thermal changes induced by a bolus injection of normal saline and thermal-dilution principles to calculate blood flow.

K033424

The Transonic Angio Flow Catheter is composed of materials that are the same type as the predicate device. The patient contacting materials have been tested in accordance with the EN Standard 30993 and/or USP class VI and are suitable for the intended use of this product.

Biocompatibility is not applicable to the meter component of the system. The meter has been tested to meet the applicable electrical safety requirements in accordance with the IEC 601 series of standards.

Substantial equivalence:

The Transonic Angio Flow Meter and catheters are similar in materials, form and intended use to the previous version of the Angio Flow meter and catheters. There are no new issues of safety or effectiveness raised by the modifications to the Transonic Angio Flow Meter and Catheter.

Safety And Effectiveness:

All finished products are tested and must meet all required release specifications before distribution. The array of testing required for release includes, but is not limited to; physical testing, visual examination (in process and finished product).

The physical testing is defined by Quality Control Test Procedure documents. These tests are established testing procedures and parameters which conform to the product design specifications.

The testing instruction records for each of the individually required procedures are approved, released, distributed and revised in accordance with document control cGMP's.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2003

Transonic Systems, Inc.
c/o Mr. Mark S. Alsberge
VP Medical and Regulatory Affairs
34 Dutch Mill Road
Ithaca, NY 14850

Re: K033424
Trade Name: Thermodilution Meter and Catheter
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II (two)
Product Code: DPW
Dated: October 22, 2003
Received: November 12, 2003

Dear Mr. Alsberge:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033424

Device Name: Transonic AngioFlow Meter and Catheter

Indications for Use:

The Transonic AngioFlow meter and catheter are indicated for use during angioplasty procedures to verify the flow before, during, and after treatment. The system is intended for the measurement of blood flow within a vascular bed utilizing a catheter-based sensor. This sensor system uses thermal changes induced by a bolus injection of normal saline and thermal-dilution principles to calculate blood flow.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K033424

12/11/03

Prescription Use X
(Per 21 CFR 801.109)

(Optional Format 3-10-98)